

Package leaflet: Information for the user

Malusone 250 mg/100 mg Film-coated tablets

atovaquone/proguanil hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Malusone is and what it is used for
2. What you need to know before you take Malusone
3. How to take Malusone
4. Possible side effects
5. How to store Malusone
6. Contents of the pack and other information

1. What Malusone is and what it is used for

Malusone belongs to a group of medicines called *antimalarials*. They contain two active ingredients, atovaquone and proguanil hydrochloride.

Malusone has two uses:

- to prevent malaria in adults and children who weigh more than 40 kg
- to treat malaria in adults and children who weigh more than 11 kg

Malaria is spread by the bite of an infected mosquito, which passes the malaria parasite (*Plasmodium falciparum*) into the bloodstream. Malusone prevents malaria by killing this parasite. For people who are already infected with malaria, Malusone also kills these parasites.

Protect yourself from catching malaria

People of any age can get malaria. It is a serious disease, but is preventable.

As well as taking Malusone, it is very important that you also take steps to avoid being bitten by mosquitoes.

- **Use insect repellent on exposed areas of the skin**
- **Wear light coloured clothing that covers most of the body**, especially after sunset as this is the time when mosquitoes are most active
- **Sleep in a screened room** or under a mosquito net impregnated with insecticide
- **Close windows and doors at sunset**, if they are not screened
- **Consider using an insecticide** (mats, spray, plug-ins) to clear a room of insects or to deter mosquitoes from entering the room
- **If you need further advice**, talk to your doctor or pharmacist

It is still possible to get malaria after taking the necessary precautions. Some types of malaria infection take a long time to cause symptoms, so the illness may not start until several days, weeks or even months after returning from abroad.

See a doctor immediately if you get symptoms such as high temperature, headache, shivering and tiredness after returning home.

2. What you need to know before you take Malusone

DO NOT take Malusone:

- if you are allergic (*hypersensitive*) to atovaquone, proguanil hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- for preventing malaria, if you have severe kidney disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Malusone.

When preventing malaria:

- if you are sick (*vomit*) within 1 hour of taking your Malusone tablet, take another dose straight away
- it is important to take the full course of Malusone. If you have to take extra tablets due to sickness, you may need another prescription.
- if you have been vomiting, it is especially important to use extra protection, such as repellents and impregnated bednets. Malusone may not be as effective, as the amount absorbed will be reduced.
- When treating malaria:
- if you have vomiting and diarrhoea tell your doctor, you will need regular blood tests. Malusone will not be as effective, as the amount absorbed will be reduced. The tests will check whether the malaria parasite is being cleared from your blood.
- if you have severe kidney disease, your doctor may want to prescribe a different medicine
- if you get a certain type of infection whilst being treated with Malusone, your doctor may prescribe another type of medicine instead of Malusone
- if the malaria is treated but then comes back repeatedly or if the malaria is caused by a certain type of parasite, your doctor may prescribe another medicine to be taken as well as Malusone

Other medicines and Malusone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way Malusone works, or Malusone itself can strengthen or weaken the effectiveness of other medicines taken at the same time. These include:

- metoclopramide, used to treat nausea and vomiting
- the antibiotics tetracycline, rifampicin and rifabutin
- efavirenz or certain highly active protease-inhibitors used to treat HIV
- warfarin and other medicines that stop blood clotting.
- etoposide used to treat cancer.

Tell your doctor if you are taking any of these. Your doctor may decide that Malusone isn't suitable for you, or that you need extra check-ups while you're taking it.

Malusone with food and drink

Take Malusone with food (preferably a fatty meal) or a milky drink, where possible. This will increase the amount of atovaquone your body can absorb, and make your treatment more effective.

Pregnancy and breast-feeding

If you are pregnant or if you have the intention to get pregnant, do not take Malusone unless your doctor recommends it.

Ask your doctor or pharmacist for advice before taking Malusone.

Do not breast-feed while taking Malusone, as the ingredients of Malusone may pass into breast milk and may harm your baby.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

If you feel dizzy, do not drive. Malusone makes some people feel dizzy. If this happens to you, do not drive, use machines or take part in activities where you may put yourself or others at risk.

3. How to take Malusone

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take Malusone with food or a milky drink, where possible.

It is best to take Malusone at the same time each day.

To prevent malaria

The usual dose for adults and adolescents weighing more than 40 kg is 1 tablet once a day, taken as below.

For children, talk to your doctor.

Malusone is not recommended for preventing malaria in children, or in adults or adolescents who weigh less than 40 kg.

There may be a different type of Malusone tablet available for children in your country.

To prevent malaria in adults:

- start taking Malusone 1 to 2 days before travelling to an area which has malaria
- continue taking it every day during your stay and then continue taking it for another 7 days after your return to a malaria-free area. Take the full course of Malusone for maximum protection. Stopping early puts you at risk of getting malaria, as it takes 7 days to ensure that any parasites that may be in your blood following a bite from an infected mosquito are killed.

To treat malaria

The usual dose for adults is 4 tablets once a day for 3 days.

For children weighing 11 kg or more:

- 11 - 20 kg – 1 tablet once a day for 3 days
- 21 - 30 kg – 2 tablets once a day for 3 days
- 31 - 40 kg – 3 tablets once a day for 3 days
- over 40 kg – dose as for adults.

Malusone is not recommended for treating malaria in children who weigh less than 11 kg.

For children who weigh less than 11 kg talk to your doctor. There may be a different type of Malusone tablet available in your country

If you take more Malusone than you should

Contact a doctor or pharmacist for advice. If possible show them the Malusone pack.

If you forget to take Malusone

It is very important that you take the full course of Malusone. If you forget to take a dose, don't worry. Just take your next dose as soon as you remember. Then continue your treatment as before. Don't take a double dose to make up for a missed dose.

If you stop taking Malusone

Take Malusone as advised by your doctor and do not stop before taking the recommended course is finished. Please talk to your doctor or pharmacist if you need any advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Look out for the following severe reactions. They have occurred in a small number of people, but their exact frequency is unknown.

Severe allergic reactions - signs include:

- rash and itching
- sudden wheezing, tightness of the chest or throat, or difficulty breathing
- swollen eyelids, face, lips, tongue or other part of the body.

Contact a doctor immediately if you get any of these symptoms. Stop taking Malusone.

Severe skin reactions:

- skin rash, which may blister and looks like small targets (central dark spots, surrounded by paler area with a dark ring around the edge) (*erythema multiforme*)
- severe widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*).

If you notice any of these symptoms contact a doctor urgently.

Most of the other side effects reported have been mild and have not lasted very long.

Very common: may affect more than 1 in 10 people

- headache
- feeling sick and being sick (nausea and vomiting)
- stomach pain
- diarrhoea

Common: may affect up to 1 in 10 people

- dizziness
- sleeping problems (insomnia)
- strange dreams
- depression
- loss of appetite
- fever
- rash
- itching
- cough
- allergic reactions

Common side effects, which may show up in your blood tests are:

- reduced numbers of red blood cells (anaemia) which can cause tiredness, headaches and shortness of breath
- reduced numbers of white blood cells (neutropenia) which may make you more likely to catch infections
- low levels of sodium in the blood (hyponatraemia)
- an increase in liver enzymes.

Uncommon: may affect up to 1 in 100 people

- anxiety
- an unusual awareness of abnormal beating of the heart (palpitations)
- swelling and redness of the mouth
- red swollen patches on the skin (hives)
- hair loss

Uncommon side effects that may show up in your blood tests:

- an increase in amylase (an enzyme produced in the pancreas).

Not known: frequency cannot be estimated from the available data

- Inflammation of the liver (hepatitis)
- blockage of the bile ducts (cholestasis)
- increase in heart rate (tachycardia)
- inflammation of the blood vessels (vasculitis) which may be visible as red or purple raised spots on

the skin but can affect other parts of the body

- seizure
- panic attacks, crying
- seeing or hearing things that are not there (hallucinations)
- nightmares
- mouth ulcers
- blisters
- peeling skin
- Increased sensitivity of the skin to sunlight (photosensitivity reactions).

Other side effects that may show up in your blood tests:

- in people with severe kidney disease, decrease in all types of blood cells (pancytopenia)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Malusone

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Malusone contains

The active substances are atovaquone and proguanil hydrochloride.

Each tablet contains 250 mg atovaquone and 100 mg proguanil hydrochloride.

The other ingredients are:

Core

Poloxamer 188 , Microcrystalline Cellulose , Low-substituted Hydroxypropyl Cellulose , Povidone K30, Sodium Starch Glycolate Type A, Silica Colloidal anhydrous, Magnesium Stearate

Coating

Hypromellose, Titanium Dioxide (E171), Iron Oxide Red (E172), Macrogol 400, Macrogol 8000

What Malusone looks like and contents of the pack

Malusone tablets are Pinkish brown to brown coloured, circular, biconvex bevelled edge film-coated tablets with '404' debossed on one side and 'G' debossed on the other side

Malusone are supplied in PVC/PVDC (clear) and hard tempered PVC/PVDC-Aluminium foil blister packs containing 12 tablets

Pack size: 12, 24, 36

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany

LAMP SAN PROSPERO S.p.A., Via della Pace, 25/A, 41030 San Prospero, Modena, Italy

PharmaCoDane ApS, Marielundvej 46A, 2730 Herlev, Denmark

Eurogenerics N.V./S.A., Heizel Esplanade B22, 1020 Brussels, Belgium

STADA Arzneimittel GmbH, Muthgasse 36/2, A-1190 Wien, Austria

This medicinal product is authorised in the Member States under the following names:

AT: Atovaquon/Proguanilhydrochlorid STADA 250 mg/100 mg Filmtabletten

BE: PROVAQUONEG 250 mg/100 mg filmomhulde tabletten

DE: Atovaquon/Proguanilhydrochlorid STADA 250 mg/100 mg Filmtabletten

DK: Malastad

FR: ATOVAQUONE/PROGUANIL EG 250 mg/100 mg comprimé pelliculé

IE: Malusone 250 mg/100 mg film-coated tablets

LU: PROVAQUONEG 250 mg/100 mg comprimé pelliculé

SE: Malastad 250 mg/100 mg filmdragerade tablettter

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